In the United States Patent and Trademark Office

Applicant: TANGELLAPALY, Mahesh and TANGELLAPALLY, Ganesh

Serial Number: 09/812291

Confirmation No.   2280

For: A Secure Electronic Healthcare Information Management Process and System

Docket Number: 01-101

Examiner: GOTTSCHALK, Martin A.

Art Unit: 3626

BRIEF ON APPEAL

Assistant Commissioner for Patents
P. O. Box 1450
Alexandria, Virginia
22313-1450

Sir:

This is an appeal from the decision of the examiner dated August 9, 2006 finally rejecting claims 1-6, 19-24 and 32-33, in the above identified application.

(i) Real party in interest

The real parties in interest are co-inventors Mahesh Tangellapally and Ganesh Tangellapally.

(ii) Related Appeals and Interferences

Appellants and their legal representative are not aware of any appeals or interferences which will directly affect or be directly affected or have a bearing on the Board's decision in the pending appeal.

(iii) Status of the Claims

Claims Rejected: 1-6, 19-24, 32 and 33
Claims Allowed: NONE
Claims Cancelled: 7-18, 25-31,
Claims Appealed: 1-6, 19-24, 32 and 33

No amendments were filed after final.

(v) Summary of Claimed Subject Matter

One aspect of the claimed subject matter is a method for managing healthcare data which allows a multiplicity of patients to assemble a virtual healthcare clinic, including the steps of:

a)   providing a central data base (see, **1** on Fig.1 and **800** on Fig. 8) capable of holding health records pertaining to the multiplicity of patients, wherein the database is accessible through at least one network connection (see, p.4, ln. 19 to p.5 ln..19);

b)   enrolling a plurality of healthcare practitioners by providing the healthcare practitioners with software operable on a computer system for reading information from medical portable access devices and writing treatment information including medical prescriptions, to the medical portable access devices, to a pharmacy directly by electronic mail and to the central database, and sending and receiving electronic mail, and interacting with the central data base over the at least one network connection (see p.5 ln. 29 to p.6 ln. 25 and **3** on Fig. 1 and **804** on Fig. 8);

c)   enrolling a plurality of pharmacies by providing the pharmacies with software operable on a computer system for reading healthcare information including medical prescriptions written by one of the plurality of enrolled healthcare practitioners from said medical portable access devices, reading medical prescriptions from the central database and reading medical prescriptions from electronic mail, reading a bar-code from a container containing a medicine and determining the identity of the medicine from the bar-code, comparing a medical prescription with the identity of the medicine, and if the identity of the medicine agrees with the medical prescription, writing a confirmation that the medical prescription has been properly dispensed to one of said medical portable access devices, and transmitting direct electronic message to the one of

said plurality of enrolled healthcare practitioners who wrote the medical prescription that the medical prescription was properly filled, and updating the central database that the medical prescription was properly dispensed (See p.6, ln. 26 to p.7, ln. 15, **4** on Fig.1, **40** on Fig.4 and **805** on Fig. 8) ;

d)   enrolling a patient member;

e)   providing said patient member with a medical portable access device;

f)   programming said medical portable access device provided to said member with healthcare information relevant to said patient member and only said patient member (see p7, ln.16 to p7, ln 27 and **3** on Fig.1, **30** Fig.3, and **803** Fig. 8);

g)   synchronizing the healthcare information on said medical portable access devices with the healthcare information contained in said central data base (see p 8 ln.1 to p 8 ln. 14); and

h)   repeating acts (d), (e), (f) and (g) for a multiplicity of patient members creating multiplicity of enrolled patient members each having a medical portable access device, and wherein any of the multiplicity of enrolled patient members may interact with any combination of enrolled healthcare practitioners and enrolled pharmacies, whereby by each of the multiplicity of enrolled patient members can create a virtual clinic of healthcare providers by choosing enrolled healthcare practitioners and enrolled pharmacies and presenting the portable access device provided to the member for updating at healthcare treatments and prescription fulfillment (see p.8, ln. 23 to p.9 ln. 2).

Another aspect of the claimed subject matter is a healthcare management system including the following:

a)   a central data base system comprising a central data base containing healthcare information pertaining to a multiplicity of patients, said central data base system accessible on at least one external network (see, **1** on Fig.1 and **800** on Fig. 8 and p. 13, ln. 29 to p. 17, ln. 5);

b)   a multiplicity of medical portable access devices, wherein each of said multiplicity of patients has at least one medical portable access device (see, **31** on Fig. 3 and p.13, ln 29 to p.17, ln. 5) ;

c)   a plurality of healthcare practitioner computer systems, each healthcare practitioner computer system comprising a device for reading and writing to any of said multiplicity of medical portable access devices, an external network communication connection, and software operating said healthcare practitioner computer system, comprising functionality for reading healthcare information pertaining to a patient from said medical portable access devices, writing a record of treatment to said medical portable access devices, writing a prescription to of said plurality of medical portable access devices, and sending at least one electronic message on the external network when a prescription is written to a portable access device (p. 17, ln. 6 to p. 18 ln. 19 and **20**, **21**,and **22** on Fig. 2); and

d)   a plurality of pharmacy computer systems, each pharmacy computer system comprising a device for reading and writing to any of said plurality of medical portable access devices, an external communication connection, a barcode reader, and software operating said pharmacy computer system, comprising functionality for reading healthcare information pertaining to a patient from said medical portable access devices, reading a prescription for a prescribed medicine from said medical portable access devices, reading a prescription for a prescribed medicine from a direct electronic message, reading a prescription a prescribed medicine from the central database reading a barcode on a package of medicine, determining the identity of the medicine from the barcode, comparing the identity of the medicine with the prescribed medicine, if the identity of the medicine and the prescribed medicine are identical, automatically sending a direct electronic confirmation over the network to an enrolled healthcare practitioner that a prescription has been properly dispensed and decrementing a refills counter pertaining to a filled

prescription to said portable access devices (see p. 20, ln. 15 to p.21, ln 25 and Fig. 4).

(vi) Grounds of rejection to be reviewed on appeal.

1. Whether claims 1-6, 19-24, and 32-33 are unpatentable under 35 USC § 103 over Goetz (US 6,421,650) in view of Mayaud (US 5,845,255) in view of Walker (US 5,883,370) and Brinkman (US 6,697,783).

2. Whether claims 5,6, and 33 are unpatentable under 35 USC § 103 over Goetz (US 6,421,650) in view of Mayaud (US 5,845,255) in view of Walker (US 5,883,370) , Brinkman (US 6,697,783) and Joao (US 6,283761).

(vii) Argument
Rejection of Claim 1,2,3,5,6, 32, and 33 under 35 U.S.C. § 103

Claim 1 stands rejected as allegedly unpatentable under 35 USC § 103 over Goetz, in view of Mayaud in view of Walker and Brinkman. The rejection is traversed with respect to claim1 on the grounds that the examiner has failed to meet the burden of establishing a *prima facie* case of obviousness.

To establish a *prima* facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations (MPEP 2142). In particular, this argument rests on the third point, to wit, "to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art". In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Claim element 1a) of the invention requires providing a central data base system capable of holding a multiplicity of health records, pertaining to a multiplicity of patients, wherein said database system is accessible through at least one network connection;

Claim elements 1e) and 1f) require providing said patient member with a medical portable access device; and programming said medical portable access device provided to said member with healthcare information relevant to said patient member and only said patient member;

Claim element 1g) requires synchronizing the healthcare information on said medical portable access device with the healthcare information contained in said central data base;

The examiner cites Goetz col. 4, lines 17-21 as evidence of a central database. This reference reads as follows: "A first embodiment of the present invention is shown functionally in FIG. 1. The system 10 comprises preferably three separate components that share a common database, where the database may be resident in the *patient* component 12 or contained on a memory device 14 such as a smart card. The three components of the system 10 in accordance with the present invention are a *patient* component 12, a physician component 16, and a pharmacist component 18." In Goetz's summary states that the invention "is capable of managing information, in a highly portable form for an individual patient."

This system does not describe a central database for storing the medical records of a multiplicity of patients as described in 1a). Goetz states that the database may be resident in the patient component or on a memory device such as a smart card. Figure 1 confirms that this is a database for one patient which is shared by the patient and his physician(s) and pharmacist.

Mayaud is a computer implemented prescription management system to assist physicians in prescribing and reviewing drugs. Among other things it does contain a database

including the drug information for many patients. It does not have a portable access device for patients.

Walker is an automated prescription filling system which prints a prescription as a bar code and allows comparison of the prescription with the NDC bar code on a drug package. Walker does not refer to a database of patient data.

Brinkman is a software-based, integrated member decision support system which provides a method for corporations, insurance carriers, health maintenance organizations, physicians, physician groups, or other clients to efficiently provide medical, pharmaceutical, and health benefit advice and information for an enrolled population. The system contains one or more databases which include member profiles, clinical information and guidelines, pharmaceutical information and guidelines, health benefit information, and optional additional information. A caller establishes communication with the system, which directs the caller to an operator who provides the caller with medical, pharmaceutical, and/or health benefit advice based on an inquiry from the caller and the information stored on the system. The system database contains member profiles but does not contain a record of all the medical treatments. It is mainly for use by patients who access it by telephone. There is no portable access device as referred to in the claims (a telephone does not have storage).

It is argued that none of the prior art references cited comprise a central database of the type claimed which holds a multiplicity of patients' records and is synchronized with patients' medical portable access devices, i.e., that the patients' medical information is distributed between the medical portable access devices and the central database. Thus none of prior art could teach or suggest claim 1g) because none of the prior art have both a central data base and patients' medical portable access devices.

Claims 2, 3, 5, and 6 depend from claim 1.

Rejection of Claim 4 under 35 USC §103

Claim 4 stands rejected on the same grounds as claims 1, 2, 3, 5, and 6. Claim 4 has additional patentability beyond Claim 1 and should be considered on its own. Claim 4 requires that a patients portable medical access device will be automatically synchronized with the central database whenever the enrolled member's portable access device is accessed by either a pharmacy computer system or practitioner computer which is connected to the central data base during access, whereby the central database contains a backup for the portable access devices and has up-to-date information.

Claim 4 could not have been taught or suggested by the prior art, since none of the prior art contains a central data base and personal portable access device, and NONE of the prior art discuss synchronizing the portable device with the central database or how it would be done. The passages sited by the final rejection (Goetz col. 15 ln. 45 to col. 16, ln. 5 and col. 5, ln. 50-51) deal with downloading certain information from the physician's or pharmacist's device to the patients device (e.g., possible allergic interactions) but not synchronizing the database with patients device.

Rejection of Claims 5,6, and 33 under 35 U.S.C.§ 103
Claims 5,6, and 33 were also rejected over Goetz, Mayaud, Walker, and Brinkman in further view of Joao (U.S. 6283761).
Joao was brought in to show health care professionals from many disciplines, biometric authentication, and digital signature. None of these claim limitations bear on the argument without Joao. Hence claims 5, 6, and 33 are non obvious for the same reasons given above without Joao.

Rejection of claims 19-24 under 35 U.S.C.§ 103
Claims 19-24 are system claims corresponding to claims 1-6 and stand rejected on the same grounds, Goetz, in view of Mayaud, Walker and Brinkman.

Rejection of Claim 19-24 are traversed because the final office action has failed to prove a *prima facie* case of obviousness. In particular, "to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior

art". In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).
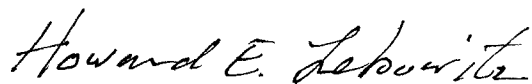
The final action fails to teach claim limitation 19a) by not providing a database system comprising a data base of health care information for a multiplicity of patients (see more detailed argument for claim 1a)).

Rejection of Claim 21 under 35 U.S.C.§ 103

Claim 21 stands rejected on the same grounds as claims 19-24. Claim 21 has additional patentability beyond Claim 19 and should be considered on its own. Claim 21requires that a patients portable medical access device will be automatically synchronized with the central database whenever the enrolled member's portable access device is accessed by either a pharmacy computer system or practitioner computer which is connected to the central data base during access, whereby the central database contains a backup for the portable access devices and has up-to-date information.

Claim 21 could not have been taught or suggested by the prior art, since none of the prior art contains a central data base and personal portable access device, and NONE of the prior art discuss synchronizing the portable device with the central database or how it would be done. The passages sited by the final rejection (Goetz col. 15 ln. 45 to col. 16, ln. 5 and col. 5, ln. 50-51) deal with downloading certain information from the physician's or pharmacist's device to the patients device (e.g., possible allergic interactions) but not synchronizing the database with patients device.

Respectfully Submitted,

Foothill Law Group, LLP

Howard E. Lebowitz

Howard E. Lebowitz
Partner
19682 Hesperian Blvd., Suite 208
Hayward, CA 94541
510-785-8070

(viii) Claims Appendix

1.   A method for managing healthcare data which allows a multiplicity of healthcare users to assemble a virtual healthcare clinic, the method comprising the ~~acts~~ steps of:

    a)   providing a central data base system capable of holding a multiplicity of health records, pertaining to a multiplicity of patients, wherein said database system is accessible through at least one ~~public~~ network connection;

    b)   enrolling a plurality of healthcare practitioners to create a plurality of enrolled healthcare practitioners, wherein enrolling a healthcare practitioner comprises providing the healthcare practitioner with software operable on a computer system for reading information from medical portable access devices and writing treatment information including medical prescriptions, to said medical portable access devices, to a pharmacy directly by electronic mail and to the central database, and sending and receiving electronic mail, and interacting with the central data base over the at least one network connection;

    c)   enrolling a plurality of pharmacies to create a plurality of enrolled pharmacies, wherein enrolling a pharmacy comprises providing the pharmacy with software operable on a computer system for reading healthcare information including medical prescriptions written by one of the plurality of enrolled healthcare practitioners from said medical portable access devices, reading medical prescriptions from the central database and reading medical prescriptions from electronic mail, reading a bar-code from a container containing a medicine and determining the identity of the medicine from the bar-code, comparing a medical prescription with the identity of the medicine, and if the identity of the medicine agrees with the medical prescription, writing a confirmation that ~~a~~ the medical prescription has been properly dispensed to one of said medical portable access devices, and transmitting direct electronic message to the one of said plurality of enrolled healthcare practitioners who wrote the medical prescription that the medical prescription was properly filled, and updating the central database that the medical prescription was properly dispensed;

    d)   enrolling a patient member;

    e)   providing said patient member with a medical portable access device;

    f)   programming said medical portable access device provided to said member with healthcare information relevant to said patient member and only said patient member;

    g)   synchronizing the healthcare information on said medical portable access devices with the healthcare information contained in said central data base; and

    h)   repeating acts (d), (e), (f) and (g) for a multiplicity of patient members creating a multiplicity of enrolled patient members each having a medical

portable access device, and wherein any of the multiplicity of enrolled patient members may interact with any combination of enrolled healthcare practitioners and enrolled pharmacies, whereby by each of the multiplicity of enrolled patient members can create a virtual clinic of healthcare providers by choosing enrolled healthcare practitioners and enrolled pharmacies and presenting the portable access device provided to the member for updating at healthcare treatments and prescription fulfillment.

2. The method of claim 1 further comprising the act of providing the multiplicity of patient members with software operable on a computer system for reading the contents of their medical portable access device, and writing updated information on the medical portable access device.

3. The method of claim 1 wherein the multiplicity of medical personal access devices comprise smart cards.

4. The method of claim 1 further comprising providing enrolled healthcare practitioners, and enrolled pharmacies, with software wherein the healthcare information in the central database pertaining to an enrolled patient member is automatically synchronized with the enrolled member's portable access device whenever the enrolled member's portable access device is accessed by either a pharmacy computer system or practitioner computer which is connected to the central data base during access, whereby the central database contains a backup for the portable access devices and has up-to-date information.

5. The method of claim 1, wherein the plurality of enrolled healthcare practitioners comprise representatives from at least three professions chosen from the group consisting of chiropractors, optometrists, dentists, psychologists, opticians, herbalists, podiatrists, and opticians.

6. The method of claim 5 further comprising providing ~~software~~ enrolled healthcare practitioners, and enrolled pharmacies, with functionality for authenticating the identity of users by a biometric measurement.

19. A healthcare information system comprising:
    a) a central data base system comprising a central data base containing healthcare information pertaining to a multiplicity of patients, said central data base system accessible on at least one external network;
    b) a multiplicity of medical portable access devices, wherein each of said multiplicity of patients has at least one medical portable access device;
    c) a plurality of healthcare practitioner computer systems, each healthcare practitioner computer system comprising a device for reading and writing to any of said multiplicity of medical portable access devices, an external network communication connection, and software operating said healthcare practitioner computer system, comprising functionality for reading healthcare information pertaining to a patient from said medical

11

portable access devices, writing a record of treatment to said medical portable access devices, writing a prescription to one of said plurality of medical portable access devices, and sending at least one electronic message on the external network when a prescription is written to a portable access device; and

d) a plurality of pharmacy computer systems, each pharmacy computer system comprising a device for reading and writing to any of said plurality of medical portable access devices, an external communication connection, a barcode reader, and software operating said pharmacy computer system, comprising functionality for reading healthcare information pertaining to a patient from said medical portable access devices, reading a prescription for a prescribed medicine from said medical portable access devices, reading a prescription for a prescribed medicine from a direct electronic message, reading a prescription a prescribed medicine from the central database reading a barcode on a package of medicine, determining the identity of the medicine from the barcode, comparing the identity of the medicine with the prescribed medicine, if the identity of the medicine and the prescribed medicine are identical, automatically sending a direct electronic confirmation over the network to an enrolled healthcare practitioner that a prescription has been properly dispensed and decrementing a refills counter pertaining to a filled prescription to said portable access devices.

20. The healthcare information system of claim 19 further comprising a multiplicity of patient computer systems, each patient computer system comprising a device for reading and writing to any of said plurality of medical portable access devices, an external communication connection, and software operating said patient computer system, comprising functionality for reading healthcare information pertaining to a patient from said portable access devices, and writing updated health history information to said portable access devices.

21. The healthcare information system of claim 20 wherein said healthcare provider computer systems, said pharmacy computer systems and said patient computer systems further comprise software functionality for optional connection to said central database system, obtaining information from said central database system, and synchronizing a portable access device to the central database system automatically whenever the portable access device is accessed while a computer system is connected to the central database system..

22. The healthcare information system of claim 21 wherein said healthcare provider computer systems, said pharmacy computer systems, and said patient computer systems further comprise a biometric measurement device for authenticating users.

23.   The healthcare information system of claim 22 wherein the healthcare provider computer systems comprise functionality requiring biometric authentication before accessing a medical portable access device.

24.   The healthcare information of claim 22 wherein said healthcare provider computer systems, said pharmacy computer systems, and said patient computer systems further comprise software functionality for requiring biometric identification of a user using said biometric measurement device prior to use

32.   The method of claim 1, wherein a plurality healthcare practitioners are unrelated except for being enrolled.

33.   The method of claim 5, wherein prescriptions contain the digital signature of a healthcare practitioner.

(ix) Evidence Appendix

NONE.

(x) Related Proceedings Appendix

NONE.